Professional Information for Medicines for Human Use

APPROVED PROFESSIONAL INFORMATION

SCHEDULING STATUS

S2

1. NAME OF THE MEDICINE

CROMOSTIL EYE DROPS 2 % *w/v*

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

CROMOSTIL EYE DROPS 10 mL & CROMOSTIL EYE DROPS 13, 5 mL.

Each ml contains Sodium Cromoglicate 20 mg(Sodium Cromoglicate 2 % w/v)

Preservative: Benzalkonium chloride 0,01 % w/v

For full list of excipients, (See section 6.1)

3. PHARMACEUTICAL FORM

CROMOSTIL EYE DROPS (Sodium Cromoglicate Eye Drops BP 2 % w/v) a clear colourless solution free from visible particulate matter.

It also contains Disodium Edetate 0,1 % w/v

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

CROMOSTIL EYE DROPS is indicated for Allergic conjunctivitis.

4.2 Posology and method of administration

For adults and children:

The recommended dose is one-two drops into each eye four times daily.

Since therapy with sodium cromoglicate is essentially prophylactic, it is important to instruct patients to maintain regular dosage.

Method of Administration

For ophthalmic use

4.3 Contraindications

Hypersensitivity to sodium cromoglicate or to any of the excipients (see section 6.1)

4.4 Special warnings and precautions for use

- Discard any remaining contents four weeks after opening the bottle.
- Soft contact lenses should not be worn during treatment period.

CROMOSTIL EYE DROPS contains benzalkonium chloride. Benzalkonium chloride is a preservative which may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using this medicine and put them back 15 minutes afterwards. Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor.

- Sodium cromoglicate can be used prophylactically.
- Patients should seek advice before they discontinue use of the product.

4.5 Interaction with other medicines and other forms of interaction

Interaction with other medicines not identified.

4.6 Fertility, pregnancy and lactation

Pregnancy

Caution should be exercised especially during the first trimester of pregnancy. Cumulative experience with sodium cromoglicate suggests that it has no adverse effects on foetal development.

Lactation

It is not known whether sodium cromoglicate is excreted in human breast milk but, on the basis of its physicochemical properties, this is considered unlikely. There is no information to suggest the use of sodium cromoglicate has any undesirable effects on the baby.

Fertility

It is not known whether sodium cromoglicate has any effect on fertility.

4.7 Effects on ability to drive and use machines

Instillation of these eye drops may cause a transient blurring of vision or cause local irritation that could impact driving or operating machinery. The patient is advised not to drive or operate machinery if affected.

4.8 Undesirable effects

Eye Disorders

Transient stinging and burning may occur after instillation. Other symptoms of local irritation have been reported rarely.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicine.

Healthcare professionals are asked to report any suspected adverse reactions to SAHPRA via The '6.04 Adverse Drug Reactions Reporting Form'. Found under SAHPRA's publications:

https://www/sahpra.org.za/Publications/Index/8

4.9 Overdose

No action other than medical observation should be necessary.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Ophthalmologicals; Other antiallergics,

ATC Code: S01GX01

Pharmacological classification: A 15.4 Ophthalmic Preparations, other.

In vitro and *in vivo* animal studies have shown that Sodium cromoglicate inhibits the degranulation of sensitised mast cells which occurs after exposure to specific antigens. Sodium cromoglicate acts by inhibiting the release of histamine and various membrane derived mediators from the mast cell.

Sodium cromoglicate has demonstrated the activity *in vitro* to inhibit the degranulation of non-sensitised rat mast cells by phospholipase A and subsequent release of chemical mediators. Sodium cromoglicate did not inhibit the enzymatic activity of released phospholipase A on its specific substrate.

Sodium cromoglicate has no intrinsic vasoconstrictor or antihistamine activity.

5.2 Pharmacokinetic properties

Sodium cromoglicate is poorly absorbed. When multiple doses of Sodium cromoglicate ophthalmic solution are instilled into normal rabbit eyes, less than 0,07 % of the administered dose of Sodium cromoglicate is absorbed into the systemic circulation (presumably by way of the eye, nasal passages, buccal cavity and gastrointestinal tract). Trace amounts (less than 0.01%) of the Sodium cromoglicate

does penetrate into the aqueous humour and clearance from this chamber is virtually complete within 24 hours after treatment is stopped.

In normal volunteers, analysis of medicine excretion indicates that approximately 0.03% of Sodium cromoglicate is absorbed following administration to the eye.

5.3 Preclinical safety data

None

Environmental Risk Assessment

Sodium Cromoglicate is a well-established active ingredient used in pharmaceutical preparations for human use. No special requirements for disposal.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Disodium Edetate Ph. Eur.

Sodium chloride Ph. Eur.

Benzalkonium chloride Ph. Eur.

Polysorbate 80 Ph. Eur.

Water for injection Ph. Eur.

6.2. Incompatibilities

None

6.3. Shelf life

Proposed shelf-life for unopened vial: 24 months.

Proposed shelf-life for opened vial: 28 days

6.4. Special precautions for storage

Store at or below 30° C.

Protect from light.

Discard after 28 days of opening the vial.

6.5. Nature and contents of container

A clear colourless solution free from visible particulate matter.

10 mL solution filled in 10mL clear translucent LDPE vial with white HIPS spike cap packed in a carton with pack insert.

13,5mL solution filled in 15mL clear translucent LDPE vial with white HIPS spike cap packed in a carton with pack insert.

6.6. Special precautions for disposal and other handling

No special requirements for disposal.

7. HOLDER OF THE CERTIFICATE OF REGISTRATION

FDC SA (PTY) LTD

Unit J3,Willows Office Park

Farm Road, The Willows, Pretoria East,

Pretoria, 0081, South Africa

8. REGISTRATION NUMBER(S):47/15.4/0671

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